

REMARKS

The above referenced application has been reviewed in light of the Office Action mailed March 27, 2009. Claims 1, 2, 5-17, and 20-26 are currently pending in this application with claims 1 and 15 being in independent form. In view of the remarks to follow, allowance of this application is respectfully requested.

As a preliminary matter, a discrepancy exists regarding the finality of the Office Action, as the Office Action Summary cover sheet indicates that the action is non-final and page 7 of the Office Action states that the action is final. To resolve the inconsistency, Applicants checked the status of the application in PAIR, which confirms "Non Final Action Mailed." Accordingly, Applicants are submitting this response in reply to the non-final office action.

In the Office Action, claims 23 and 25 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner states that the claims recite that the trapezoidal transverse cross-section includes exactly four sides, but that the specification is silent as to exactly how many sides are in the trapezoidal transverse cross-section.

According to §2163.02 of the MPEP, "[a]n applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, *figures*, diagrams, and formulas that fully set forth the claimed invention" (Emphasis added).

Figure 6, reproduced below on page 10 of this response, shows an embodiment of the second needle end having a trapezoidal transverse cross-section including exactly four sides. Therefore, the subject matter contained in claims 23 and 25 (i.e., "wherein the

trapezoidal transverse cross-section includes exactly four sides") was in fact described in the specification (i.e., at least in Figure 6). In view of the foregoing, it is respectfully submitted that the rejection of claims 23 and 25 should be withdrawn.

Claims 1, 2, 5-6, 8, 10, 12-17, and 21-22 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,002,564 to McGregor et al. (hereinafter, McGregor). Applicants respectfully submit that independent claims 1 and 15 are allowable over McGregor because McGregor fails to disclose each and every element of independent claims 1 and 15.

According to §2131 of the MPEP, to anticipate a claim, the reference must teach each and every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Independent claims 1 and 15 recite a surgical needle comprising, *inter alia*, an elongated needle body having a first end and a second needle end having a transition area, a proximal portion of the second needle end disposed proximally of the transition area including a first length having a trapezoidal transverse cross-section and a distal portion of the second needle end disposed distally of the transition area including a second length having a triangular transverse cross-section.

The cross-sections of the second needle end are shown in FIGS. 6 and 7, reproduced hereinbelow. Specifically, the trapezoidal transverse cross-section is shown in Figure 6 and the triangular transverse cross-section is shown in Figure 7.

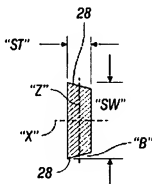


FIG. 6

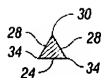
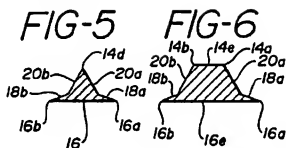


FIG. 7

The words “trapezoidal” and “triangular” are adjectives modifying the noun “cross-section.” As such, the base word of “trapezoidal” is “trapezoid” which is defined by www.dictionary.com unabridged, based on the Random House Dictionary, Random House, 2009, as “a quadrilateral plane figure having two parallel and two non-parallel sides,” as shown in Figure 6 above. The base word “triangle” of “triangular” is defined by the same dictionary as “a closed plane figure having three sides and three angles,” as shown in Figure 7 above.

McGregor discloses a surgical needle configuration with spatula geometry having a six-sided cross-sectional portion and a tapered end having a five-sided cross-section. The “six-sided cross-sectional portion results from a parallel or tapered pair of upper and lower surfaces connected by needle walls and a pair of fluted edges. At the tapered end of the needle, the upper surface alternates resulting in a five-sided cross-section.” (See Abstract of McGregor, lines 1-6.) The tapered end and the spatula area of the needle are shown in FIGS. 5 and 6, reproduced hereinbelow.



Applicants respectfully submit that McGregor fails to anticipate each and every element of claims 1 and 15, in that McGregor fails to show or disclose a proximal portion of the second needle end disposed proximally of the transition area including a first length having a trapezoidal transverse cross-section and a distal portion of the second needle end disposed distally of the transition area including a second length having a triangular transverse cross-section. The five- and six-sided needle of McGregor is neither triangular (three-sided) nor trapezoidal (four-sided).

Since McGregor does not disclose each and every element of claims 1 and 15, Applicants respectfully submit that the rejection of claims 1 and 15 as being anticipated under 35 U.S.C. §102(b) in view of McGregor should be withdrawn.

As claims 2, 5-6, 8, 10, 12-14, and 21-22 depend from claim 1 and contain all of the limitations recited therein, and claims 16-17 depend from claim 15 and contain all of the limitation recited therein, Applicants respectfully submit that claims 2, 5-6, 8, 10, 12-17, and 21-22 are also not anticipated under 35 U.S.C. §102(b) over McGregor.

Claims 7, 9, 20, and 23-26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over McGregor. As stated above, with regard to claims 1 and 15, McGregor fails to show or disclose a proximal portion of the second needle end disposed proximally of the transition area including a first length having a trapezoidal transverse cross-section

and a distal portion of the second needle end disposed distally of the transition area including a second length having a triangular transverse cross-section.

The Examiner states that the extra sides or fluted edges are only present to create thickness and to further improve tissue penetration. Therefore, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a trapezoidal transverse cross-section with exactly four sides or the triangular transverse cross-section with exactly three sides, depending on the desired thickness as long as the needle facilitates better tissue penetration, as well as a smaller wound area.

Applicants respectfully disagree. McGregor clearly indicates the need for “a needle with improved sharpness which also reduces penetration resistance, as well as reducing wound opening area and minimizing tissue distortion.” (Col. 1, lines 53-56). Moreover, McGregor discloses a needle as described below:

Generally, along the spatulated portion of the needle 10, the cross-sectional shape of the needle will be six-sided. At the tapered end 12 of the needle 10, *the cross-sectional shape of the needle 10 becomes five-sided, and provides reduced cross-sectional area. This enables better tissue penetration, as well as smaller wound area.* In order to improve tissue penetration further, it is generally preferable to have each of the fluted edges contain an included angle between 1° and 35°, with about 22° being preferred.

(Emphasis added, Col. 3, line 15-24). Nowhere does McGregor disclose or suggest that the fluted edges are *only* present to create thickness and to *further* improve tissue penetration. As stated above, “better tissue penetration” is provided by the “reduced cross-sectional area” of the five-sided shape. It is this “better tissue penetration” which may be even further improved by adjusting the included angle of the fluted edges.

Furthermore, McGregor specifically states that *triangular needles require refining* as triangular shaped cross-section needles “usually sacrifice one criterion for an increased benefit in another criterion.” (Col. 1, lines 50-52). Accordingly, McGregor explicitly discloses a needle having a spatulated geometry and states that the needle is more readily adapted to refined surgical techniques as “[t]his refined needle improves tissue penetration, wound closure and tissue distortion.” (Col. 2, lines 24-25). Thus, McGregor is clearly teaching that the spatulated needle is a refinement over a triangular needle. One skilled in the art would not look to changing the geometry of the needle as McGregor clearly reveals the deficiencies of a three-sided needle and indicates that **a triangular needle cannot satisfy all of the desired needle criteria concurrently.**

Therefore, McGregor does not teach or suggest all of the claim limitations of claims 7, 9, 23, and 24 which depend from claim 1, and claims 20, 25, and 26 which depend from claim 15. For at least this additional reason, claims 7, 9, 20, and 23-26 define over McGregor and are in condition for allowance. Therefore, Applicants respectfully request withdrawal of the rejection of claims 7, 9, 20 and 23-26 under 35 U.S.C. §103(a) over McGregor has been overcome.

In view of the foregoing remarks, Applicants submit that all of the claims are in proper format and are patentably distinct from the references of record and are in condition for allowance. The Examiner is invited to contact the undersigned at the telephone number listed below with any questions concerning this application.

Respectfully submitted,



Paul J. Natof
Reg. No.: 54,333
Attorney for Applicants

Carter, DeLuca, Farrell & Schmidt, LLP
445 Broad Hollow Road - Suite 420
Melville, New York 11747
Tel.: (631) 501-5700
Fax: (631) 501-3526

Mailing Address:
Covidien
60 Middletown Avenue
North Haven, CT 06473

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